REMARKS

This paper is responsive to an Official Action that was issued in this case on July 18, 2007. In that Action, the Examiner rejected claims 1-40 under 35 USC §102 as being anticipated by U.S. Published Patent Application 2003/0031993 to Pugh.

In this paper, applicants propose several amendments to the Description. These amendments are for the purpose of providing the serial numbers of related cases. Those serial numbers were not available when this case was filed. Entry of these missing serial numbers is respectfully requested.

Applicant further proposes an amendment to claim 25 to bring it into conformance with claim. It is believed that this amendment, which simply adds language that appears in claim 1 to claim 25, will not raise new issues for consideration or require and additional search. Reconsideration of the claim rejections is respectively requested in light of the proposed amendment and the following comments.

The Examiner's primary reference is a medical exam teaching and measurement system by Pugh. The system disclosed by Pugh includes a simulator, which a manikin with simulated anatomical structures within, sensors in the simulator, a feedback presentation unit, and software to access performance.

Before addressing the claim language, applicant will address some of the relevant differences between Pugh and the claimed invention. The main points of contention between the Examiner and applicant are (1) the appropriateness of the Examiner's interpretation of certain claim language as well as (2) the appropriateness of ignoring certain functional language.

The Examiner states that "Pugh discloses that the simulator may include anatomical parts inside, such as a spleen or liver. The simulated parts may be used for simulating palpation or manual assessment by a user. Therefore, the end effector could comprise a user's hand." (Citations omitted.)

1. **Confusion.** The skin interaction techniques that are performed in applicant's invention, which include (1) skin stretch, (2) palpation, and (3) occlusion, are performed via a practitioner's hand, NOT the end effector, which the applicant considers to be two different things. The "end effector," which in the illustrative embodiment is a "needle/catheter module 218" (*see*, *e.g.*, FIGs. 3 and 8), is used to simulate the vascular access technique

itself; that is, IV insertion, central venuous-line placement, peripherally-inserted central catheter, *etc.*

2. **Missing Elements.** The Examiner argues (pg. 14 of Office Action) that the various anatomical parts in Pugh's manikin are, effectively, a disclosure of "a first device for performing a first skin-interaction technique...." The Examiner further argues that the "end effector" can be a practitioner's hand. In this regard, the Examiner notes that the hand or "end effector" can be used to perform "palpation techniques." Query, if the "first device" is one of the simulated anatomical parts within Pugh's manikin, then what is the "receiver [that] ... receives an end effector"? There is no disclosure in Pugh of a receiver that receives an end effector.

3. **Function/Use Limitations.** The Examiner stated that applicant claims "intended use" functions. In particular, the Examiner stated that no consideration was given to claim language after the word "for" in the claims. According to the Examiner, terminology after the word "for" in an apparatus claim is nothing more than intended use. There appears to be some confusion on this point.

MPEP 2114, which was cited by the Examiner in support of her position, states two propositions:

1. APPARATUS CLAIMS MUST BE STRUCTURALLY DISTINGUISHABLE FROM THE PRIOR ART.
2. THE MANNER OF OPERATING THE DEVICE DOES NOT DIFFERENTIATE APPARATUS CLAIMS FROM THE PRIOR ART.

These propositions are undoubtedly correct; however, the Examiner misinterprets their meaning.

Under proposition number 1, MPEP 2114 states that "while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function."

Note that the language from MPEP 2114 says "**features** ... may be recited ... functionally" and "**claims** ... must be distinguished ... in terms of structure rather than function."

This provision does not direct an Examiner to ignore functional limitations, in fact, MPEP explicitly authorizes them. This provision simply says that an apparatus claim must be structurally distinguishable from the prior art.

The applicant has included a limitation in claim 1 that recites "a first device for performing a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure." That is a functional limitation which becomes part of the structural definition of the apparatus. The functional language or description, which is the language "for performing a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure," modifies the phrase "first device." And this modifying language affects the universe of "first device[s]" that could be a part of the claimed apparatus. The Examiner cannot simply ignore terminology after the word "for;" EVERY word in this limitation is properly credited with meaning.

Applying MPEP 2114, claim 1 must be structurally distinguishable from Pugh. Thus, if Pugh does not include an element that is "a first device for performing a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure," then claim 1 is structurally distinguishable over Pugh. In other words, again, this functional limitation becomes part of the structural definition of the claimed apparatus.

An example of an apparatus claim that would *not* be distinguishable based on functional issues would be one in which all the limitations, whether functionally defined or structurally explicit, are disclosed in the prior art, and the only difference is the function/use for the claimed apparatus. For example, if the prior art apparatus includes limitations A, B, C, and D and is used for pumping fluids through the intestine, and the claimed invention recites A, B, C, and D and includes a "wherein" or "for" clause that recites that the apparatus is "for pumping fluids through the vascular system," then the claim under consideration is probably not distinguishable from the prior art.

Another example of an apparatus claim that would not be distinguishable based on functional issues would be one in which the only difference between the prior art and the claimed invention is the function or use for a commonplace element of the claimed apparatus. For example, assume the claimed invention recites a reciprocating pump for pumping fluids through a particular tube that is part of the claimed apparatus. Further assume that this tube is not shown in the prior art; rather, in the prior art, a reciprocating pump is used to move fluid through a channel. In this hypothetical, there is nothing that would distinguish the reciprocating pump in the claimed invention and the prior art – other than its use. It's still a reciprocating pump.

In the present case, the claim doesn't simply recite "a first device." Rather, it recites "a first device for performing a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure." The first device must perform this function, which, frankly, seriously limits the universe of "first devices" that would be suitable for use. And this limitation becomes part of the structural definition of the apparatus.

4. **Broadest Reasonable Interpretation.** Applicant is well aware that the Office must give claim terms their broadest reasonable meaning. But the MPEP's requirement of a "reasonable" interpretation means that the reading must comport with (1) the specification and (2) must be consistent with the interpretation of those skilled in the art.

As MPEP 2111 states:

> During patent examination, the pending claims must be "given their broadest reasonable interpretation **consistent with the specification.**" The Federal Circuit's en banc decision in Phillips v. AWH Corp., 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) expressly recognized that the USPTO employs the "broadest reasonable interpretation" standard:
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> The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction **"in light of the specification as it would be interpreted by one of ordinary skill in the art.**" In re Am. Acad. of Sci. Tech. Ctr., 367 F.3d 1359, 1364[, 70 USPQ2d 1827] (Fed. Cir. 2004)....
>
> The broadest reasonable interpretation of the claims **must also be consistent with the interpretation that those skilled in the art would reach**. In re Cortright, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999) (The Board's construction of the claim limitation "restore hair growth" as requiring the hair to be returned to its original state was held to be an incorrect interpretation of the limitation. The court held that, consistent with applicant's disclosure and the disclosure of three patents from analogous arts using the same phrase to require only some increase in hair growth, one of ordinary skill would construe "restore hair growth" to mean that the claimed method increases the amount of hair grown on the scalp, but does not necessarily produce a full head of hair.).

To only way to read the Pugh reference onto the applicant's claims is to interpret the claim language without regard to the specification and without the regard to the knowledge and perspective of one skilled in the relevant art.

A. **End Effector.** In particular, the Examiner alleges that the phrase "end effector," as used in the applicant's description and claims, properly encompasses a human hand. This interpretation is not supported by the specification nor would one skilled in the art ever consider a human hand to be an end effector.

The term "end effector," which is borrowed from the field of robotics, means "a device or tool connected to the end of a robot arm." (www.whatis.com) It is the robot's "last link," hence the word "end." The end effector is used to accomplish a task, hence the word "effector." The end-effector can hold a tool, or the end-effector itself may be a tool.

In applicant's invention, there is no robotic arm, so the definition is not precisely applicable. Rather, applicant's have defined it to mean a device, a tool or instrument.

In applicant's definition of "end effector" at paragraph [0025], it is noted that "[t]he structure of the end effector depends on the intended task. For example, in the illustrative embodiment, the end effector is intended to be used to simulate a vascular access procedure, and it is therefore implemented as a catheter-needle module." One of the present inventors received a PhD. in robotics. Notwithstanding the Examiner's position, that inventor was adamant that no one skilled in the art of robotics or haptics would consider a human hand to be an "end effector." Although an "end-effector is loosely comparable to a human's hand," (www.learnaboutrobots.com) no one skilled in the art of robots or haptics would ever consider the human hand to be an end effector. If a declaration to that effect is required, it can be provided.

As a consequence, the broadest reasonable interpretation of the phrase "end effector" does not include "a human hand."

B. **Vascular Access Procedure.** The Examiner alleges that Pugh discloses vascular access procedures. In particular, the Examiner cites to Pugh's disclosure, at paragraph [0062], wherein it is stated that "[b]y hand, the surgeon can feel where the solid tumor ends and a major blood vessel begin for example." The Examiner further asserts that the standard definition of vascular means "supplied with or made up of such channels and especially blood vessels." Therefore, according to the Examiner, "Pugh does teach simulating a vascular-access procedure." (Office Action, page 14.)

It is applicant's contention that Pugh does not disclose any "vascular access procedure." The phrase "vascular access procedure" is a term of art, as a quick search on-line will demonstrate. The Applicant provides examples of vascular access procedures in the specification at paragraph [0003]: "IV insertion, central venous-line placement, peripherally-inserted central catheter."

Doing an on-line search provides a variety of references to the meaning of "vascular access procedure."

For example, "Answers.com" states that vascular access procedures involve "the use of flexible tubes (catheters) that remain inserted into blood vessels for weeks or months, and provide a means of infusing antibiotics, chemotherapy, pain medications, or nutritional support into patients, and enable blood samples to be taken from patients." (www.answers.com)

Radiologyinfo.org provides the following explanation of a "vascular access procedure:

> A vascular access procedure is designed for patients who need intravenous (IV) access for a considerable time, longer than seven to 10 days. A simple IV is effective in the short term but is far from ideal when, for instance, a patient needs a course of chemotherapy, several weeks of IV antibiotic treatment or long-term IV feeding. Some patients have veins that make it difficult to place an IV and those patients may benefit from a vascular access placement. A vascular access catheter is a long, thin tube that is placed in a vein in the arm, in the neck or in the chest just beneath the collarbone. The tube then is threaded into a major vein in the middle of the chest. In many conditions, having this type of tube inserted provides a simple and painless means of drawing blood, or delivering drugs, nutrients or both. This also spares the patient the discomfort and stress of repeated needle sticks. These so-called *central catheters* can remain in place for weeks, months or even years.

In summary, the phrase "vascular access procedure" is a term of art. Applicant's use of the phrase in the specification is consistent with its well-accepted meaning. The Examiner's interpretation of the phrase is not consistent with its well accepted meaning to those skilled in the art.

C. ***Skin-interaction technique that is used in conjunction with a simulated vascular-access procedure.*** The skin interaction techniques that are used in conjunction with a vascular access procedure are very specific. These techniques include: (1) palpation, (2) occlusion, and (3) skin stretch. As disclosed in U.S. Pat. Appl. 10/807,017, which is incorporated by reference into the present case:

> **[0007]** Palpation is a multi-purpose technique. It can be used by a practitioner to locate hidden veins. Veins might not be readily locatable due to the advanced age or poor physical condition of the patient, the procedure being performed, or due to other reasons. To palpate for hidden veins, the practitioner pats the skin. Palpation can also be used to obtain information about a candidate vein once it has been located. In particular, the practitioner can determine whether the candidate vein is sufficiently engorged. A practitioner can also determine, via palpation, whether a vein is sufficiently straight (at an intended insertion point) for catheterization. To palpate a vein to obtain this type of information, the practitioner moves one or two fingers lightly over the candidate vein.
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> **[0008]** Occlusion is a technique that is performed during catheterization. Specifically, a finger or thumb of the non-dominant hand is used to apply pressure on the catheter at the insertion point so that no blood leaks out of the hub of the catheter when the stylet is removed. To practice the third technique mentioned above—the skin-stretch technique—the thumb of the non-dominant hand pulls a patient's skin, rendering it taut. This reduces a patient's level of discomfort and anchors the vein so that it doesn't move during angiocatheter insertion.

To the extent that Pugh discloses "palpation techniques" for checking organs, which can be performed on the organ surface (*i.e.*, within the body) or on the skin, such techniques are different than the palpation techniques that are used "in conjunction with a simulated vascular-access procedure," such as to palpate for hidden veins or to determine if a vein is sufficiently straight for catheterization.

Furthermore, it should now be clear that the recited skin stretch technique, as practiced "in conjunction with a simulated vascular-access procedure" and involves using the thumb of the non-dominant hand to pull a patient's skin taut, is not disclosed by Pugh. The citations provided by the Examiner on this point (*i.e.*, FIGs. 14C, 15, 16) simply shows dissection of the body, wherein a part of the body tissue is being held apart (by retractors, etc) to permit access to the inside of the body.

With the foregoing in mind, we turn now to the independent claims:

Claim 1 recites an apparatus comprising:

> pseudo skin;
>
> a *receiver*, wherein said receiver receives an *end effector*; and
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> a first device for performing *a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure*,
>
> wherein said receiver and said first device are disposed beneath said pseudo skin.

Pugh does not disclose:

1. a receiver for receiving an end effector; or
2. a first device for performing a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure.

There is no "end effector" disclosed by Pugh. But even if a practitioner's hand were to be considered to be an "end effector," then what is the "receiver" that is disclosed by Pugh? If the Examiner considers the receiver to be an internal organ, which seems to be a stretch, then what is the "first device" that is disclosed by Pugh?

Pugh does not disclose either items 1 or 2; therefore, claim 1 is allowable over Pugh. All claims that are dependent on claim 1 are likewise allowable. The recitation of further patentable features in such dependent claims provides a secondary basis for their patentability.

Claim 25 discloses an apparatus comprising:

> a housing;
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> an end effector, wherein said end effector is inserted into said housing during the performance of a simulated vascular-access procedure; and
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> a plurality of mechanisms, wherein said plurality of mechanisms are contained completely within said housing, and wherein said plurality of mechanisms include:
>
> (a) a first mechanism is for simulating a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure; and
>
> (b) a second mechanism for receiving said end effector.

Pugh does not disclose either of the first or the second mechanism recited in claim 25. As a consequence, claim 25 is allowable over that reference. All claims that are dependent on claim 25 are likewise allowable. The recitation of further patentable features in such dependent claims provides a secondary basis for their patentability.

Claim 35 recites an apparatus comprising:

> a pseudo skin;
>
> a plurality of mechanisms with which a user interacts for simulating a vascular-access procedure, wherein said plurality of mechanisms are disposed under said skin; and
>
> a housing, wherein said housing contains said plurality of mechanisms.

Pugh does not disclose a plurality of mechanisms with which a user interacts for simulating a vascular-access procedure. As such, claim 35 is allowable over Pugh. All claims that are dependent on claim 35 are likewise allowable. The recitation of further patentable features in such dependent claims provides a secondary basis for their patentability.

Respectfully,
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